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PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Paul GILSON et al.	)	
	)	
Application No.: 09/838,544	)	Group Art Unit: 3737
	)	
Filed: April 20, 2001	)	Examiner: Unknown
	)	
For: AN EMBOLIC PROTECTION SYSTEM	)	
	)	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

CLAIM FOR PRIORITY

Under the provisions of Section 119 of 35 U.S.C., Applicants hereby claim the benefit of the filing date of: Ireland Patent Application No. 970789, filed November 7, 1997; Ireland Patent Application No. 980267, filed April 8, 1998; Ireland Patent Application No. 2001/0258, filed March 16, 2001; Ireland Patent Application No. 2001/0260, filed March 16, 2001; Ireland Patent Application No. 2001/0261, filed March 16, 2001; and International Patent Application No. PCT/IE00/00045, filed April 20, 2000 for the above-identified United States Patent Application.

In support of Applicants' claim for priority, certified copies of the priority applications are filed herewith.

Respectfully submitted,

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Dated: December 28, 2001

By: _____
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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	970789
Date of Filing	7 November 1997
Applicant	SALVIAC LIMITED, an Irish company of 39-40 Upper Mount Street, Dublin 2, Ireland.

Dated this 12th day of September 2001.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

970789

FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT 1992

The Applicant(s) named herein herby request(s)
[X] the grant of a patent under Part II of the Act
[ ] the grant of a short-term patent under Part III of the Act
on the basis of the information furnished hereunder.

1. Applicant(s)

SALVIAC LIMITED
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Ireland
an Irish Company

2. Title of Invention
A device

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous Filing Date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) and addresse(s) of person(s) believed by the Applicant(s) to be the inventor(s)

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Eamon Brady,
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an Irish Citizen of Ridge Road, Gloster, Birr, County Offaly, Ireland

970788

5. Statement of right to be granted a patent (Section 17(2) (b))

The Applicant derives the right to apply by virtue of a Deed of Assignment dated November 7 1997

6. Items accompanying this Request

(i)	[X]	prescribed filing fee (IRP 117)
(ii)	[X]	specification containing a description and claims
	[ ]	specification containing a description only
	[X]	Drawings referred to in description or claims
(iii)	[ ]	An abstract
(iv)	[ ]	Copy of previous application(s) whose priority is claimed
(v)	[ ]	Translation of previous application whose priority is claimed
(vi)	[ ]	Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)
The following information is applicable to the present application which is made under Section 24 -

Earlier Application No.
Filing Date:

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name & Address

Cruickshank & Co. at their address recorded for the time being in the register of Patent Agents is hereby appointed Agents and address for service, presently 1 Holles Street, Dublin 2.

9. Address for service (if different from that at 8)

Signed Cruickshank & Co.

By:- C. Schmitt Executive.

Agents for the Applicant

Date 7/11/1997

 APPLICATION No. E 970789

"A Device"

Introduction

The invention relates to an embolic protection device.

The term "STROKE" is used to describe a medical event whereby blood supply to the brain or specific areas of the brain is restricted or blocked to the extent that the supply is inadequate to provide the required flow of oxygenated blood to maintain function. The brain will be impaired either temporarily or permanently, with the patient experiencing a loss of function such as sight, speech or control of limbs. There are two distinct types of stroke, haemorrhagic and embolic. This invention addresses embolic stroke.

Medical literature describes carotid artery disease as a significant source of embolic material. Typically, an atherosclerotic plaque builds up in the carotid arteries. The nature of the plaque varies considerably, but in a significant number of cases pieces of the plaque can break away and flow distally and block bloodflow to specific areas of the brain and cause neurological impairment. Treatment of the disease is classically by way of surgical carotid endarterectomy whereby, the carotid artery is cut and the plaque is physically removed from the vessel. The procedure has broad acceptance with neurological complication rates quoted as being low, somewhere in the order of 6% although claims vary widely on this.

Not all patients are candidates for surgery. A number of reasons may exist such that the patients could not tolerate surgical intervention. In these cases and an increasing number of candidates that are surgical candidates are being treated using transcatheter

techniques. In this case, the evolving approach uses devices inserted in the femoral artery and manipulated to the site of the stenosis. A balloon angioplasty catheter is inflated to open the artery and an intravascular stent is sometimes deployed at the site of the stenosis. The action of these devices as with surgery can dislodge embolic material which will flow with the arterial blood and if large enough, eventually block a blood vessel and cause a stroke.

There is a need for an embolic protection device which will overcome this problem.

Statements of Invention

According to the invention, there is provided an embolic protection device comprising a filter element for placing in a desired position, the filter element providing a pathway for blood and having means for capturing, retaining and removing undesired embolic material.

In one embodiment of the invention, the pathway has means for constricting flow to capture undesired embolic material.

In another embodiment of the invention, the filter has a proximal end and a distal end, openings in the proximal end being larger than openings in the distal end, the proximal end openings being sized to allow the flow of blood and embolic material to enter the filter element and the distal end openings being sized to allow the flow of blood while capturing undesired emboli within the filter element.

In a further embodiment of the invention, the filter element includes storage means to store captured undesired

embolic material in the filter element. Preferably, the storage means comprises additional storage pathways within the filter element. Preferably, the filter element defines a three dimensional matrix.

In another embodiment of the invention, the filter element is of a polymeric porous structure. In a further embodiment of the invention, the matrix comprises a porous structure dimensioned to entrap embolic material ranging in size from 500 microns to 3500 microns. In a still further embodiment of the invention, the filter element is compressible and/or foldable for loading into a delivery device to deliver the filter element to a desired location in the compressed or folded state.

In one embodiment of the invention, the filter element has material removed from its structure to aid compressibility.

In another embodiment of the invention, the filter element has material removed from its structure to provide specific sizing in relation to the size of embolic material trapped.

In a further embodiment of the invention, the filter element has pathways that are inter-linked such that the flow rate through the filter may be tailored.

In another embodiment of the invention, the filter element has a distal end which is tapered such that there is a smooth transition in lateral stiffness to improve the manoeuvrability of the filter element in the vascular system.

In a further embodiment of the invention, the filter element has a soft distal portion to aid in atraumatic

transport through the vasculature system. Preferably, the filter element has circumferential grooves to reduce the lateral flexibility of the filter element.

In one embodiment of the invention, the filter element has a tapered proximal end to facilitate retrieval by a removal catheter.

In another embodiment of the invention, the filter element has inlet holes that close on pulling back into a retrieval catheter to ensure retention of any collected emboli.

In a further embodiment of the invention, the filter element captures embolic material of a size large enough to impair the function of the organ receiving the blood. Preferably, the filter element captures embolic material of a size greater than 100 microns. Most preferably, the filter element captures embolic material of a size greater than 200 microns. Most preferably, the filter element captures embolic material of a size greater than 500 microns.

In one embodiment of the invention, the filter element is sized for complete coverage of a vessel cross-section that allows passage of blood and blood components.

In a still further embodiment of the invention, there is provided a device having means for placing over a medical guidewire.

In another embodiment of the invention, there is provided a device which may be placed under a balloon or stent delivery catheter.

In a further embodiment of the invention, there is provided a device having means for insertion through, femoral, brachial, radial, subclavian or other arterial puncture by means of a transcatheter approach.

In one embodiment of the invention, there is provided a device for protection of neurological function which is inserted for the duration of a surgical intervention at or near the site of surgical opening.

In another embodiment of the invention, there is provided a device which is used bi-laterally allowing sufficient cerebral blood flow to maintain neurological function during procedures with a high risk of generating clot such as electrophysiological treatment of coronary arrhythmias.

In a further embodiment of the invention, there is provided a device including a delivery catheter in which an external sheath is used to provide push during delivery and is subsequently removed to allow maximum space in the vascular cross-section.

In one embodiment of the invention, the external sheath is joined to the filter element by a joining means. Preferably, the joining means is a removable shrink tube. Preferably, the joining means is a removable split collar. Most preferably, the joining means is a removable clip.

In another embodiment of the invention, the delivery catheter has a central lumen for at least part of it's length to allow it to track over a steerable guidewire.

In a further embodiment of the invention, the filter element is released from the catheter by removal proximally of the external sheath which extends to the outside of the vasculature.

In one embodiment of the invention, the delivery catheter has an external covering which extends beyond the push element to define a filter retention sleeve.

In another embodiment of the invention, the delivery catheter has a spring component with a localised stepwise increasing pitch to alter stiffness characteristics to suit the target vasculature.

In a further embodiment of the invention, the delivery catheter has a spring component with a localised gradually increasing pitch to alter stiffness characteristics to suit the target vasculature.

In one embodiment of the invention, the filter element is mounted on a collapsible support structure which is movable between a collapsed position for deployment and an extended in-use position, means being provided for retaining the support structure in the collapsed position. Preferably, the support structure comprises support arms. Preferably, the support arms are formed from a shape memory material. Most preferably, the support arms are formed from Nitinol.

In one embodiment of the invention, the support arms are configured to open co-axially with the filter shaft such that they may be restrained for removal by pulling proximally on an appropriately dimensioned sheath.

In another embodiment of the invention, the filter element has an associated support structure with a pre-shaped spiral arrangement such that it provides radial support to the filter element.

In a further embodiment of the invention, the filter support structure is adapted to fold into the collapsed position when pulled into a removal catheter.

In one embodiment of the invention, the filter element comprises a flexible shaped polymeric component.

In another embodiment of the invention, the shaped polymeric component is constructed such that fluid flow through the component assists in opening the component from the collapsed position.

In a further embodiment of the invention, the shaped polymeric component is flexible and opens to make circumferential contact with the vessel wall by way of using the pressure drop across the exit filter face.

In one embodiment of the invention, the filter element is directly bonded onto a steerable medical guide wire incorporating a slidable sheath that is movable to deploy the filter.

In another embodiment of the invention, there is provided a device incorporating a medical guidewire with a flexible segment of wire distal to the filter so as to provide steerability of the wire particularly prior to it being deployed.

In a further embodiment of the invention, there is provided a device incorporating a medical guide wire with a soft distal segment so as to provide a tip section that will be atraumatic.

In a still further embodiment of the invention, there is provided a device with a porous coating on a distal end of

the filter element only with a means for opening and closing the filter by slidable motion.

In one embodiment of the invention, the filter element incorporates proximal tapering such that it may be pulled proximally into a sheath for removal in order that such pulling action will effectively reduce the diameter of the filter and assist retrieval.

In another embodiment of the invention, the filter element has a porous structure that can be deployed and closed by way of a slidable motion, the closure thereof caused by way of snap-fit to a protruding rim that allows the support elements be pulled proximally, thus closing the structure with the filter membrane attached.

In a further embodiment of the invention, there is provided a device having a filter element which permits the incorporation of a medical guide wire in the outer wall of the filter element to facilitate the incorporation of large ingress holes on the proximal end of the filter element.

In one embodiment of the invention, the filter element comprises a mesh work structure with large proximal ingress holes and small distal egress holes wherein the mesh structure can collapse into a small diameter delivery catheter and expand upon deployment to a shape which is remembered by the mesh structure either through its shape memory characteristics or elastic memory characteristics.

In another embodiment of the invention, the filter element comprises a mesh work structure wherein the expansion of the filter element within the vessel causes blood flowing through the vessel to flow through the filter element due

to the filter element forcing the vessel to conform to its external dimensions.

In a still further embodiment of the invention, there is provided a filter retrieval system for use with the device as claimed in any preceding claim comprising a longitudinal catheter with a deformable tip to assist the pull back of the filter into it.

In another embodiment of the invention, there is provided a system incorporating a filter, a delivery catheter and a retrieval catheter for temporary filtration of the vascular system during an interventional procedure.

Brief Description of Drawings

The invention will be more clearly understood from the following description thereof given by way of example only with reference to the accompanying drawings in which:-

Fig. 1 is a side view of an embolic protection device according to the invention, in use;

Fig. 2 is a side view of the device of Fig. 1 in a pre-loaded position for insertion;

Fig. 3A is a side view illustrating one method of fixing the device to catheter;

Fig. 3B is a side view of an embolic protection device incorporating the fixing of Fig. 3A;

Fig. 4 is a side view illustrating another method of fixing;

Fig. 5 is an end view of a split collar used in the fixing of Fig. 4;

Fig. 6 is a side view illustrating a further method of fixing;

Fig. 7 is an end view of a jubilee clip used in the fixing of Fig. 6;

Fig. 8 is a side view of one filter element used in the device of the invention;

Fig. 9 is a side view of another filter element;

Fig. 10 is a side view of the filter element of Fig. 8 being removed;

Fig. 11 is an isometric view of another filter element in an in-use placed configuration;

Fig. 12 is a side view of the filter element of Fig. 11 in a retracted position for insertion and withdrawal;

Figs. 13 to 15 are side views of another filter element in different positions;

Figs. 16 and 17 are side views of part of a further filter element with a snap fit retrieval arrangement;

Fig. 18 is a perspective, partially cross-sectional view of another embolic protection device shown mounted in a vessel;

Figs. 19a to 19c are perspective views illustrating the formation of a collapsible filter support for use in the device of Fig. 18;

Figs. 20 to 22 are perspective views of other filter elements;

Fig. 23 is an elevational view of another filter element;

Fig. 24 is a sectional view taken along the line XXIV-XXIV of Fig. 23;

Fig. 25 is a sectional view taken along the line XXV-XXV of Fig. 23;

Fig. 26 is an enlarged detail view of portion of the filter; and

Fig. 27 is an expanded view of the filter element of Fig. 23.

Detailed Description

Referring to the drawings there are illustrated various embolic protection devices according to the invention. The devices, in general, comprise a filter element for temporary placing in a desired position during a surgical procedure, typically using a guidewire and catheter. The filter element provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure. The filter element containing the retained embolic material is removed when the interventional procedure is completed. In this way the patient is protected against the risk of

stroke or other complications caused by the release of undesired embolic material during the procedure.

In one embodiment of the device it will be used in an over the wire transcatheter configuration. The clinician will cross the lesion with a steerable guidewire. The cerebral protection device will then be threaded over the guidewire and will be placed distal to the site of the lesion being treated. By means of actuation, or other means, the filter is deployed into the vessel and will capture emboli that are generated or dislodged during balloon inflation and stent placement. The device consists of a filter attached to a shaft that can run over the primary crossing guidewire.

Referring initially to Figs. 1 and 2 in this case the filter element consists of a compressible porous structure polymeric foam element 1 overmoulded onto or joined to a polymeric or metallic tube or spring or other hollow element 2. The foam filter element 1 is compressed into a housing or pod 3 to advance it to the required location. Once in situ the housing 3 is withdrawn or the filter element 1 is advanced. This action allows the compressed filter element 1 to expand to the required size and occlude the vessel 4 except for the path or paths provided through the filter 1. The filter 1 is designed to provide a pathway or multiple pathways through for blood cells and other blood constituents but to capture emboli of a size greater than the filter pore size. Blood flow rate is maintained by forming the filter element such that a local pressure drop across the filter is minimised.

The filter element 1 in this case is of a porous structure or polymeric foam which has a open cell structure with a typical density less than 150 kg per cubic meter. Preferably the density will be less than 100 kg per cubic

meter and ideally will be less than 50 kg per cubic meter. The filter properties may be achieved through appropriately sizing the pores of the foam or additionally by removing material to create appropriately sized pathways for blood to flow through and means of capturing larger sized particles. A number of configurations for this will be described that can tailor both the sizing and flow rate characteristics of the filter either independently or simultaneously. The actuation and deployment of the filter are achieved by providing relative motion between the filter 1 and the covering element 3. It is not desirable that the outer sheath moves relative to the sheath during manipulation. Motion may be prevented by fixing the inner element to the catheter in a number of different ways. In the embodiment described this is achieved by way of having a sheath covering the inner element and filter to which it is fixed. As illustrated in Figs. 3A and 3B the fixing may be achieved by means of a shrink wrap tube 5 that is shrunk to capture both the covering spring 6 and the inner element. Once the filter is in the desired position, the shrink-wrap joint is broken using the tab 7 to allow the outer sheath to be removed proximally and leave the tube and filter in place.

A number of other workable arrangements could be used to join the tube and sheath. A split collar arrangement 10 (Figs. 4 & 5) could be used that was removable by means of unlocking a screw or a number of screws or an arrangement such as a jubilee clip 11 (Figs. 6 & 7) which could be loosened to free the bond between the components.

Another method that could be used to temporarily fix the inner element to the outer sheath is a Hemostasis High Pressure Touhy Borst Y adapter. This commercially available adapter is needed to enable the physician to

flush the sheath before being inserted into the artery. The outer sheath may be permanently attached to this adapter. The inner tube runs through the Touhy Borst section of the adapter and thus through the centre of the sheath. Tightening the Touhy Borst section releases this grip, thus allowing the inner tube and the outer shaft to move relative to each other once again.

The design of the filter element 1 is shown in a typical embodiment in Fig. 8, where a foam substrate has material removed to create a series of pathways 20 for the blood to flow through but which would cause a restriction for embolic material to prevent it going through the filter. The pathways or channels 20 may be machined using a variety of methods such as laser cutting with excimer, YAG, CO2, or other laser type, freezing and machining or lost wax machining. A number of arrangements are possible with the sizing reflective of the requirements. In the configuration shown, the inlet holes are in the 0.5 - 3mm range to capture large emboli while the outlet holes are in the 200 micron range. These can be easily varied to filter differing sized particles from a variety of fluid media in a variety of vessel sizes.

The filter media can be bonded to the tubing substrate by way of a variety of available technologies such as mechanical, solvent or adhesive bonding and overmoulding in an arrangement such that the substrate is placed in the mould and the polymer material is then shot into the mould and forms a bond at the interface between the substrate and the polymer element. Additionally, the foam or porous element could be extruded onto or bonded to a substrate.

It will be noted that the filter element 1 has a rounded distal end 21 to facilitate insertion and the proximal end

22 is tapered to facilitate withdrawal. Alternatively, as illustrated in Fig. 9 the distal end 23 may be tapered.

Referring particularly to Fig. 10 at the end of the interventional procedure, the device can be withdrawn by means of advancing a large bore catheter 25 to the proximal end 22 of the filter 1 and pulling the filter 1 into the catheter 25. The filter 1 will compress and seal the filter openings after the initial taper is drawn into the catheter 25. Once the filter 1 has been withdrawn fully into the catheter 25 it can then be readily removed from the patient. The filter 1 will contain the captured emboli.

In another embodiment of the invention as illustrated in Figs. 11 to 15, an arrangement of spokes 30 covered with a membrane or porous fabric or mesh 31 can be folded down into a delivery sheath or pod for subsequent deployment in the target vessel. The design consists of a substrate shaft 33 onto which are radially or circumferentially bonded a series of pre-shaped wires 30. The wires 30 are joined on the proximal end into a movable tube 32 mounted on the substrate shaft 33 and at the distal end into a fixed tube 34. The tube 32 can move proximally and distally to the extent that it will open and close the assembly in a manner similar to an umbrella and thereby occlude the vessel. The spokes 30 may be fabricated in a range of metallic, polymeric and composite materials. The frame is covered with a porous material 31, whose pore size is selected to allow the media through, effectively creating a screen filter. The covering fabric 31 could be bonded to the frame 30 by means of casting a material such as a polyurethane or PET onto the pre-formed shape. The film may then be lazed or made porous by other means such as mechanical or heat punching or by chemical etching. Additionally, incorporating a soluble particle in the

polymer matrix, subsequent removal of the particle would render the polymer porous. Control of porosity is achieved by tailoring the ratio and distribution of the particulate within the polymer matrix.

When the assembly is configured longitudinally a sheath or pod may be slid over it to cover it. As with the previous embodiment, the loaded catheter is positioned in the required location by threading it over the guidewire. Once the desired location has been reached, the sheath may be moved back and allow the assembly be exposed in the vessel. A sleeve 35 can then be moved forward to open or deploy the assembly. The relative sizing and choice of materials operates such that the sleeve 35 will not slide on the inner tubing unless an external force is applied to move it. When deployed, the device will remain open and catch whatever embolic material is moving towards the brain. At the end of the procedure, a pre-shaped component advanced over the inner tube will dock with the movable tube 32 and allow it to be slid towards the proximal end of the device with the result that the structure is closed. A larger sheath can then separately be advanced to the site of the filter and the filter may be pulled or manipulated proximally into it. When withdrawn into the catheter, the device may then be removed either over the guidewire or with it.

Referring to Figs. 16 and 17 there is illustrated another embolic protection device. In this case the filter element has a design based on a shaped thin film component bonded onto the tubing substrate. A wide number of shapes could be made to work in the application. An element which through it's preshaped form will open into a framework 40 when the restraining force is removed is attached to a tubing substrate 41. The frame element 40 can be manufactured from a range of metallic or polymeric

components such as a shape memory alloy like Nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from deformation sufficiently to cause the film component to open. Otherwise a mechanical movement or actuation can cause the device to open. The shaped film component is attached over the frame 40. The film component can be formed by a number of known commercial technologies. These include blow-moulding, dip casting, solution casting, spin casting and film welding as well as adhesive joining. The object is to produce a formed shape that can be opened in the vessel to a size and shape to occlude it. Filtration is achieved by creating a pattern or series of openings in the proximal and distal ends of the element that allows emboli and blood to enter the device but having a range of smaller openings in the distal end to allow the blood to pass through to the distal vasculature while retaining the emboli.

While being delivered to the required site, the filter element is covered or restrained by a sheath. By withdrawing the sheath or advancing the filter device, the filter is uncovered and opens to occlude the vessel. During the procedure, the filter acts to capture all embolic material that attempts to flow distally. At the end of the procedure, a sheath is advanced to the proximal end of the device and the filter is pulled proximally into it with the retained emboli captured. In this design configuration, the emboli can easily be removed for analysis afterwards.

The invention above is described as it relates to a device that can be used over a medical guidewire. The opportunity exists to configure the invention in a manner that it could in itself be used as the primary crossing device. All of the filter designs described above could

be mounted onto either the over the wire or the primary crossing device as described hereunder. For a primary crossing device the filter would be bonded to a solid substrate. Some benefits would accrue in that the inner diameter onto which the filter could be wrapped down would be smaller because it would not need to move over another instrument. Fig. 18 illustrates the differences involved. The filter element 1 is mounted on the substrate shaft 33. A collapsible filter support element 50 is mounted on the substrate shaft 33 at a proximal end of the filter 1. The support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel.

Referring to Figs. 20 to 22 there is shown alternative constructions of filter element comprising a compressible filter 1 shown in an expanded position with a large inlet opening 60 and smaller outlet openings 61. A collapsible wire support 62 is provided at a proximal end of the filter 1. The wire support 62 is collapsible with the filter 1 within a housing or part for deployment and upon release expands to support the filter 1 in the vessel 4.

An alternative filter arrangement is shown in Figs. 23 to 27. In this case, the filter comprises a Nitinol mesh which is expandable from a collapsed position shown in Fig. 23 for deployment to an expanded in use position shown in Fig. 27.

For a primary crossing device, the distal end of the device will be flexible and atraumatic. This can be achieved by a number of means such as fabricating a spring or polymeric element to be flexible enough to deflect when it comes into contact with the walls of the vessel. The tip section would be mounted distally to the filter

element. An intermediate section of the device will house the filter 1 which would be covered prior to deployment. A sheath could be fully the length of the device or attached by an actuator to a shorter sheath that covers the filter only. The proximal section of the device will provide a platform for the balloon dilatation and stent devices. The provision of a platform may be achieved as shown by removing the proximal covering to expose a wire or spring assembly. Alternatively, the whole proximal section could function as the platform. Essentially, to function as the platform for balloon catheter and stent, the devices should be sized with an outside diameter dimension that allows free movement of the catheter systems over it. Typical industry standards for coronary products permit free movement of devices over a .014" diameter while peripheral angioplasty applications use a .035" OD.

The invention is not limited to the embodiments hereinbefore described which may be varied in construction and detail.

CLAIMS

1. An embolic protection device comprising a filter element for placing in a desired position, the filter element providing a pathway for blood and having means for capturing, retaining and removing undesired embolic material.

2. A device as claimed in claim 1 wherein the pathway has means for constricting flow to capture undesired embolic material.

3. A device as claimed in claim 1 or 2 wherein the filter has a proximal end and a distal end, openings in the proximal end being larger than openings in the distal end, the proximal end openings being sized to allow the flow of blood and embolic material to enter the filter element and the distal end openings being sized to allow the flow of blood while capturing undesired emboli within the filter element.

4. A device as claimed in any preceding claim wherein the filter element includes storage means to store captured undesired embolic material in the filter element.

5. A device as claimed in claim 4 wherein the storage means comprises additional storage pathways within the filter element.

6. A device as claimed in any preceding claim wherein the filter element defines a three dimensional matrix.

7. A device as claimed in claim 6 wherein the filter element is of a polymeric porous structure.

8. A device as claimed in claim 6 or 7 wherein the matrix comprises a porous structure dimensioned to entrap embolic material ranging in size from 500 microns to 3500 microns.

9. A device as claimed in any preceding claim wherein the filter element is compressible and/or foldable for loading into a delivery device to deliver the filter element to a desired location in the compressed or folded state.

10. A device as claimed in any preceding claim wherein the filter element has material removed from its structure to aid compressibility.

11. A device as claimed in any preceding claim wherein the filter element has material removed from its structure to provide specific sizing in relation to the size of embolic material trapped.

12. A device as claimed in any preceding claim wherein the filter element has pathways that are inter-linked such that the flow rate through the filter may be tailored.

13. A device as claimed in any preceding claim wherein the filter element has a distal end which is tapered such that there is a smooth transition in lateral stiffness to improve the manoeuvrability of the filter element in the vascular system.

14. A device as claimed in any preceding claim wherein the filter element has a soft distal portion to aid in atraumatic transport through the vasculature system.

15. A device as claimed in any preceding claim wherein the filter element has circumferential grooves to reduce the lateral flexibility of the filter element.

16. A device as claimed in any preceding claim wherein the filter element has a tapered proximal end to facilitate retrieval by a removal catheter.

17. A device as claimed in any preceding claim wherein the filter element has inlet holes that close on pulling back into a retrieval catheter to ensure retention of any collected emboli.

18. A device as claimed in any preceding claim wherein the filter element captures embolic material of a size large enough to impair the function of the organ receiving the blood.

19. A device as claimed in claim 18 wherein the filter element captures embolic material of a size greater than 100 microns.

20. A device as claimed in claim 18 wherein the filter element captures embolic material of a size greater than 200 microns.

21. A device as claimed in claim 18 wherein the filter element captures embolic material of a size greater than 500 microns.

22. A device as claimed in any preceding claim wherein the filter element is sized for complete coverage of a vessel cross-section that allows passage of blood and blood components.

23. A device as claimed in any preceding claim having means for placing over a medical guidewire.

24. A device as claimed in claim 23 which may be placed under a balloon or stent delivery catheter.

25. A device as claimed in any preceding claim having means for insertion through, femoral, brachial, radial, subclavian or other arterial puncture by means of a transcatheter approach.

26. A device as claimed in any preceding claim for protection of neurological function which is inserted for the duration of a surgical intervention at or near the site of surgical opening.

27. A device as claimed in any preceding claim which is used bi-laterally allowing sufficient cerebral blood flow to maintain neurological function during procedures with a high risk of generating clot such as electrophysiological treatment of coronary arrhythmias.

28. A device as claimed in any preceding claim including a delivery catheter in which an external sheath is used to provide push during delivery and is subsequently removed to allow maximum space in the vascular cross-section.

29. A device as claimed in claim 28 wherein the external sheath is joined to the filter element by a joining means.

30. A device as claimed in claim 29 wherein the joining means is a removable shrink tube.

31. A device as claimed in claim 29 wherein the joining means is a removable split collar.

32. A device as claimed in claim 29 wherein the joining means is a removable clip.

33. A device as claimed in any of claims 28 to 32 wherein the delivery catheter has a central lumen for at least part of it's length to allow it to track over a steerable guidewire.

34. A device as claimed in any of claims 28 to 33 wherein the filter element is released from the catheter by removal proximally of the external sheath which extends to the outside of the vasculature.

35. A device as claimed in any of claims 28 to 34 wherein the delivery catheter has an external covering which extends beyond the push element to define a filter retention sleeve.

36. A device as claimed in any preceding claim wherein the delivery catheter has a spring component with a localised stepwise increasing pitch to alter stiffness characteristics to suit the target vasculature.

37. A device as claimed in any preceding claim wherein the delivery catheter has a spring component with a localised gradually increasing pitch to alter stiffness characteristics to suit the target vasculature.

38. A device as claimed in any preceding claim wherein the filter element is mounted on a collapsible support structure which is movable between a

collapsed position for deployment and an extended in-use position, means being provided for retaining the support structure in the collapsed position.

39. A device as claimed in claim 38 wherein the support structure comprises support arms.

40. A device as claimed in claim 39 wherein the support arms are formed from a shape memory material.

41. A device as claimed in claim 40 wherein the support arms are formed from Nitinol.

42. A device as claimed in claim 39 wherein the support arms are configured to open co-axially with the filter shaft such that they may be restrained for removal by pulling proximally on an appropriately dimensioned sheath.

43. A device as claimed in any preceding claim wherein the filter element has an associated support structure with a pre-shaped spiral arrangement such that it provides radial support to the filter element.

44. A device as claimed in any preceding claim wherein the filter support structure is adapted to fold into the collapsed position when pulled into a removal catheter.

45. A device as claimed in any preceding claim wherein the filter element comprises a flexible shaped polymeric component.

46. A device as claimed in claim 45 wherein the shaped polymeric component is constructed such that fluid

flow through the component assists in opening the component from the collapsed position.

47. A device as claimed in any preceding claim wherein the shaped polymeric component is flexible and opens to make circumferential contact with the vessel wall by way of using the pressure drop across the exit filter face.

48. A device as claimed in any preceding claim wherein the filter element is directly bonded onto a steerable medical guide wire incorporating a slidable sheath that is movable to deploy the filter.

49. A device as claimed in any preceding claim incorporating a medical guidewire with a flexible segment of wire distal to the filter so as to provide steerability of the wire particularly prior to it being deployed.

50. A device as claimed in any preceding claim incorporating a medical guide wire with a soft distal segment so as to provide a tip section that will be atraumatic.

51. A device as claimed in any preceding claim with a porous coating on a distal end of the filter element only with a means for opening and closing the filter by slidable motion.

52. A device as claimed in any preceding claim wherein the filter element incorporates proximal tapering such that it may be pulled proximally into a sheath for removal in order that such pulling action will effectively reduce the diameter of the filter and assist retrieval.

53. A device as claimed in any preceding claim wherein the filter element has a porous structure that can be deployed and closed by way of a slidable motion, the closure thereof caused by way of snap-fit to a protruding rim that allows the support elements be pulled proximally, thus closing the structure with the filter membrane attached.

54. A device as claimed in any preceding claim having a filter element which permits the incorporation of a medical guide wire in the outer wall of the filter element to facilitate the incorporation of large ingress holes on the proximal end of the filter element.

55. A device as claimed in any preceding claim wherein the filter element comprises a mesh work structure with large proximal ingress holes and small distal egress holes wherein the mesh structure can collapse into a small diameter delivery catheter and expand upon deployment to a shape which is remembered by the mesh structure either through its shape memory characteristics or elastic memory characteristics.

56. A device as claimed in any preceding claim wherein the filter element comprises a mesh work structure wherein the expansion of the filter element within the vessel causes blood flowing through the vessel to flow through the filter element due to the filter element forcing the vessel to conform to its external dimensions.

57. A filter retrieval system for use with the device as claimed in any preceding claim comprising a

longitudinal catheter with a deformable tip to assist the pull back of the filter into it.

58. A system incorporating a filter, a delivery catheter and a retrieval catheter for temporary filtration of the vascular system during an interventional procedure.

CRUICKSHANK & CO.,

DEVICE PRELOADED

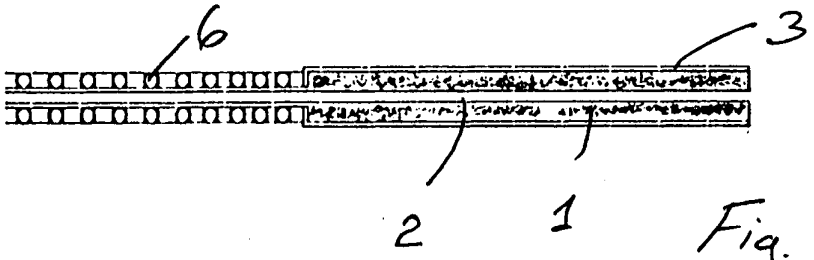


Fig. 2

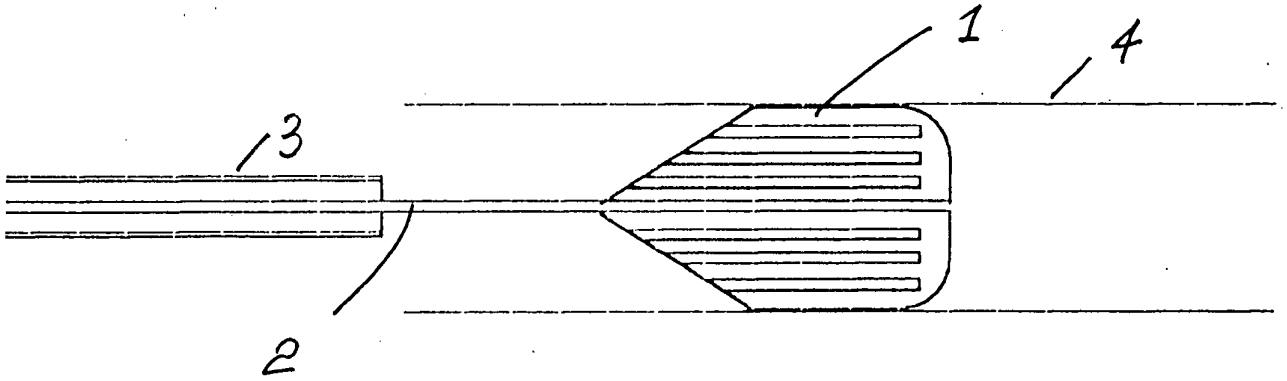
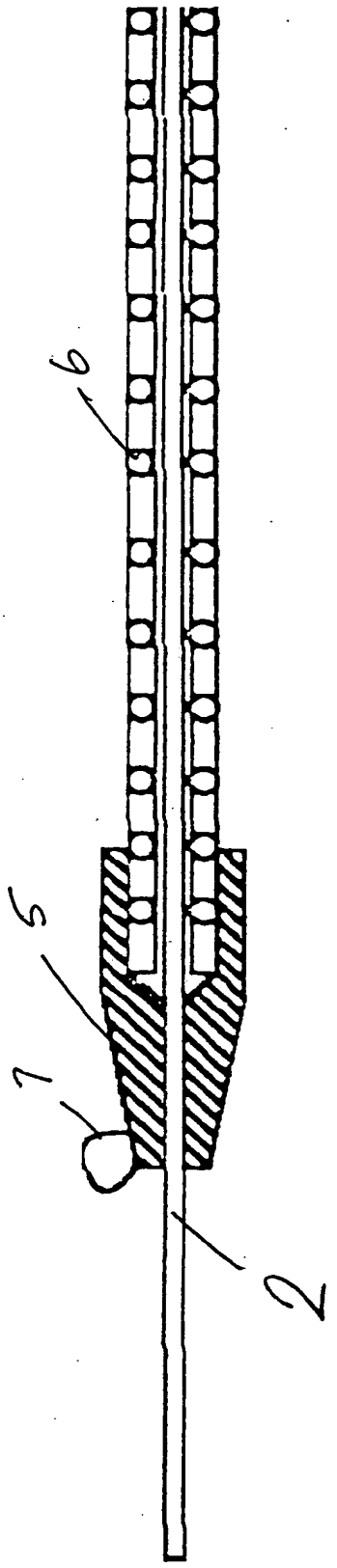


Fig. 1

Fig. 3A



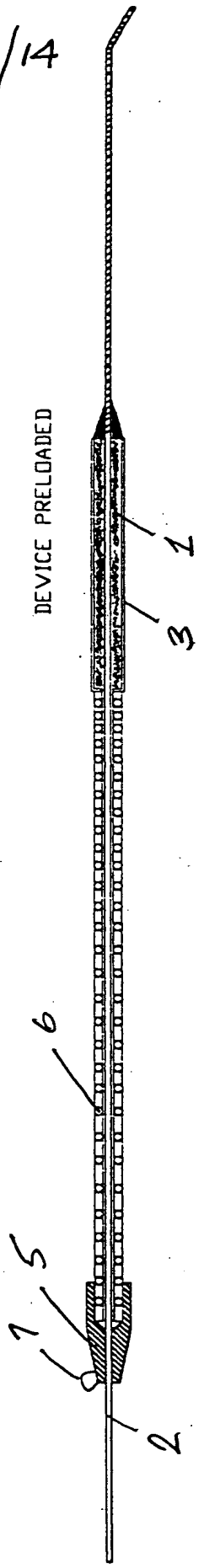
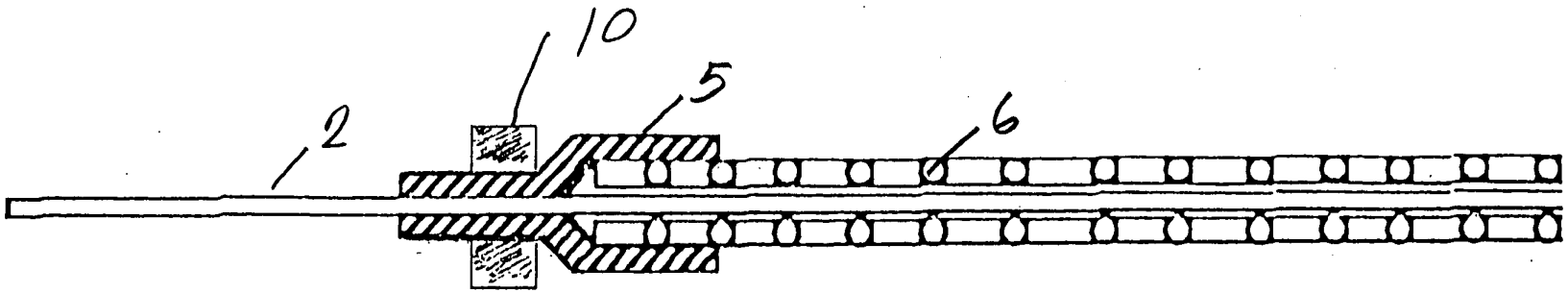


Fig. 3B



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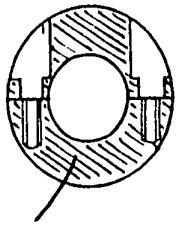
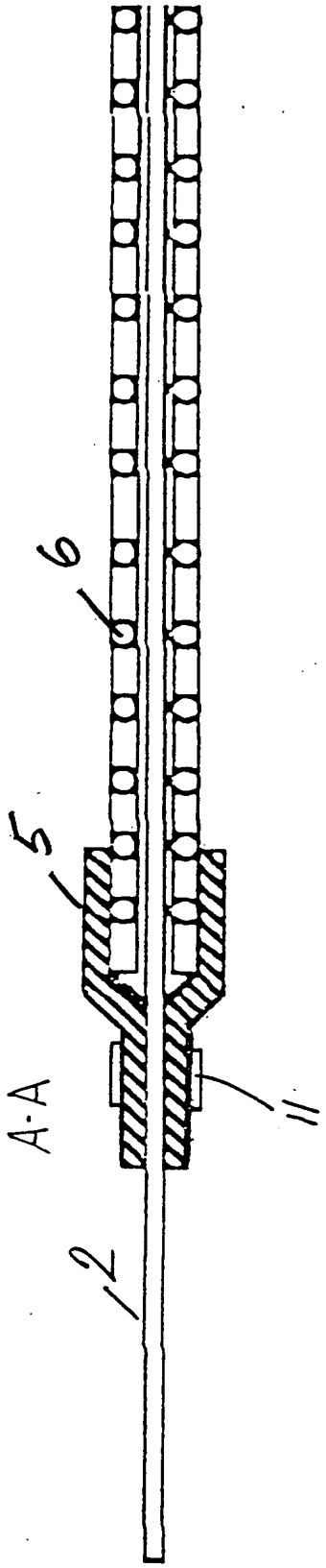


Split Collar

Fig. 5



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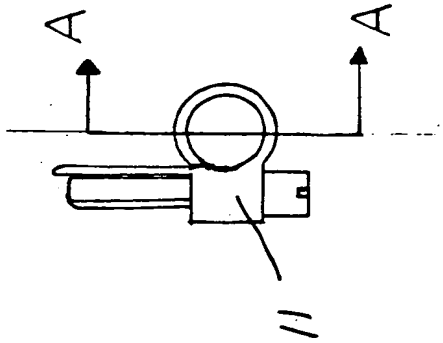
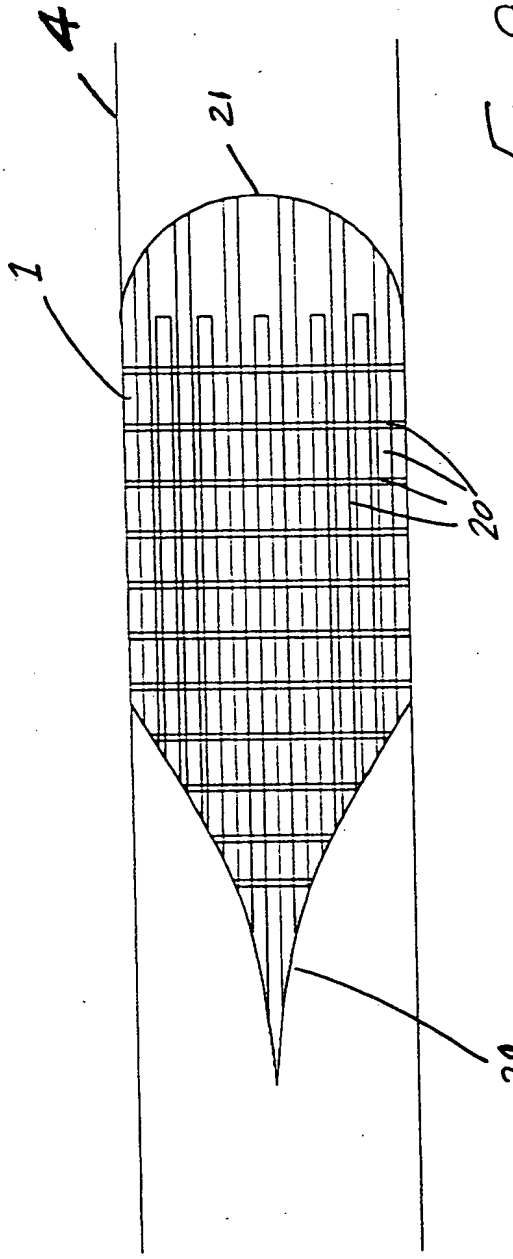


Fig. 7



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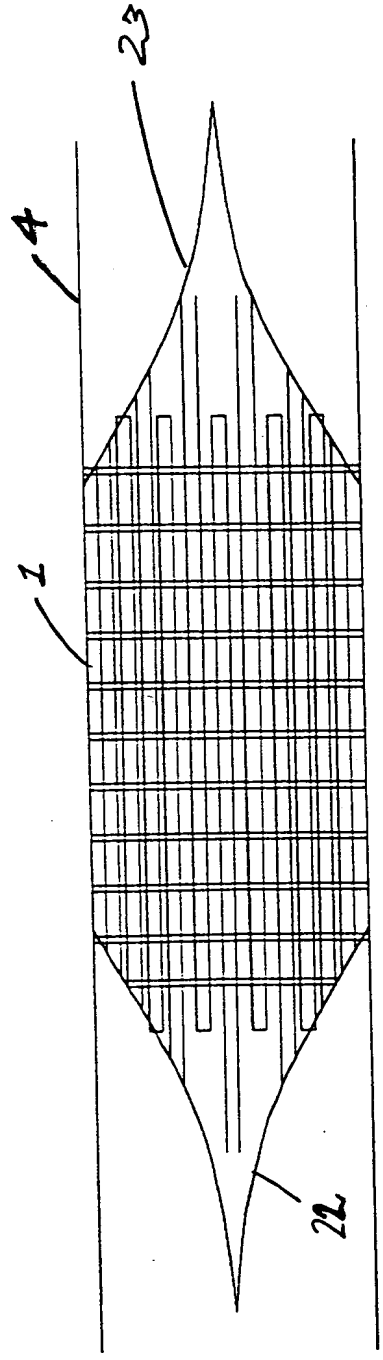

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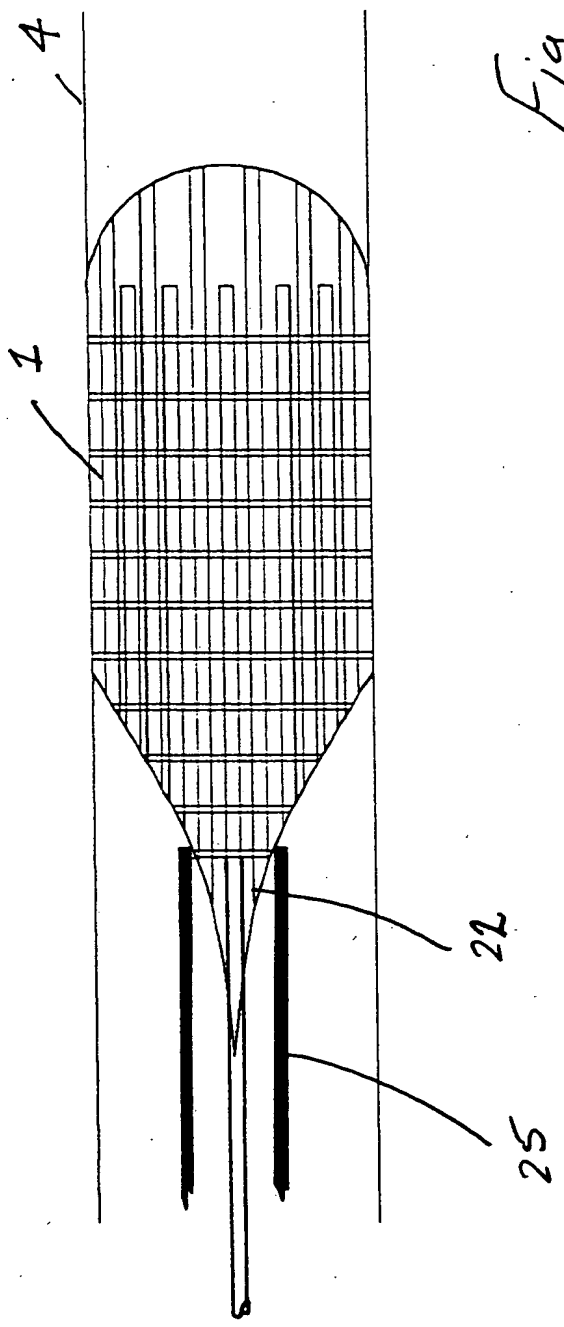


Fig. 10

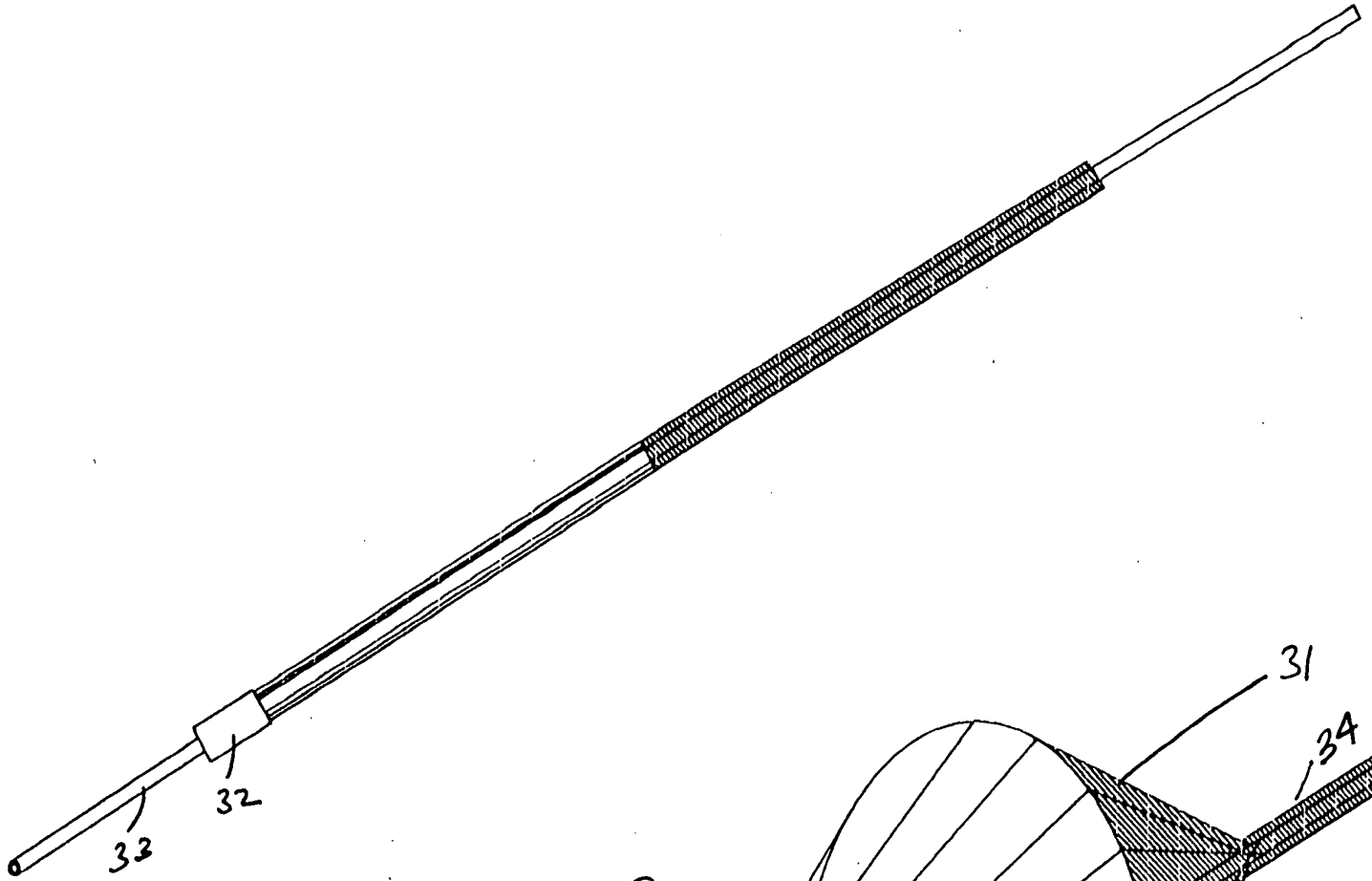


Fig. 12

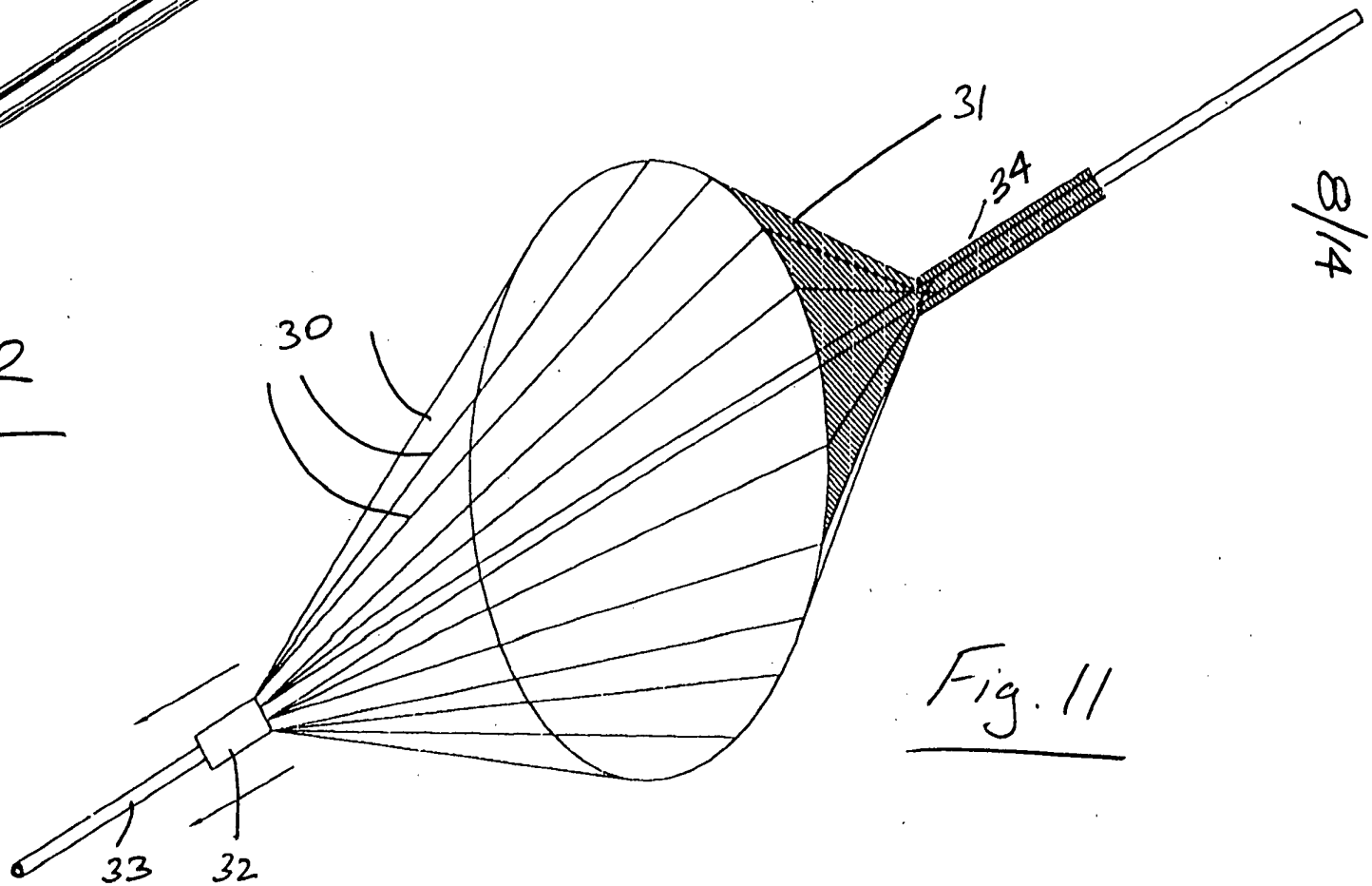


Fig. 11

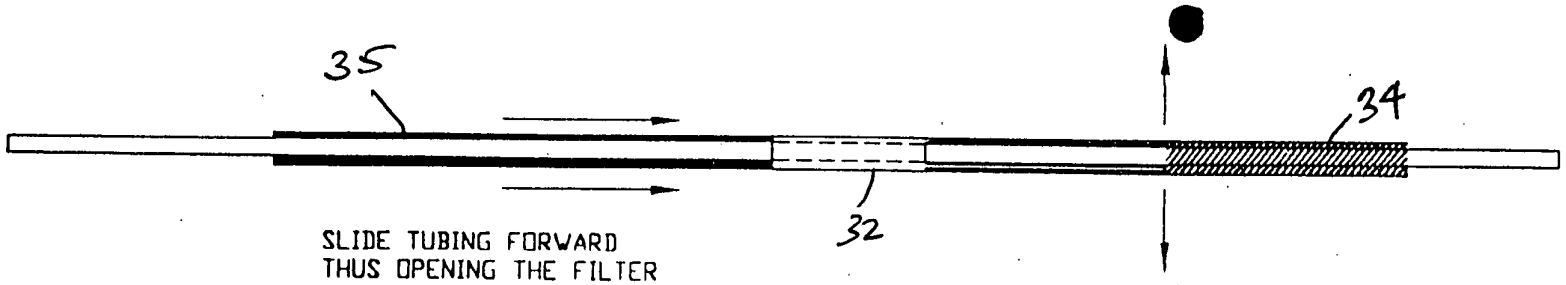


Fig. 13

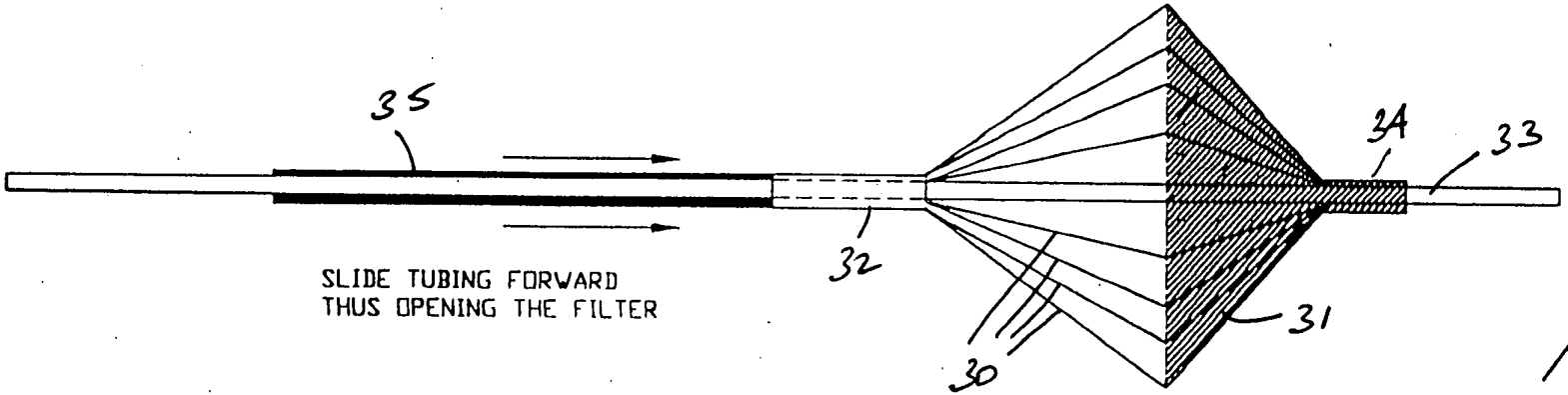


Fig. 14

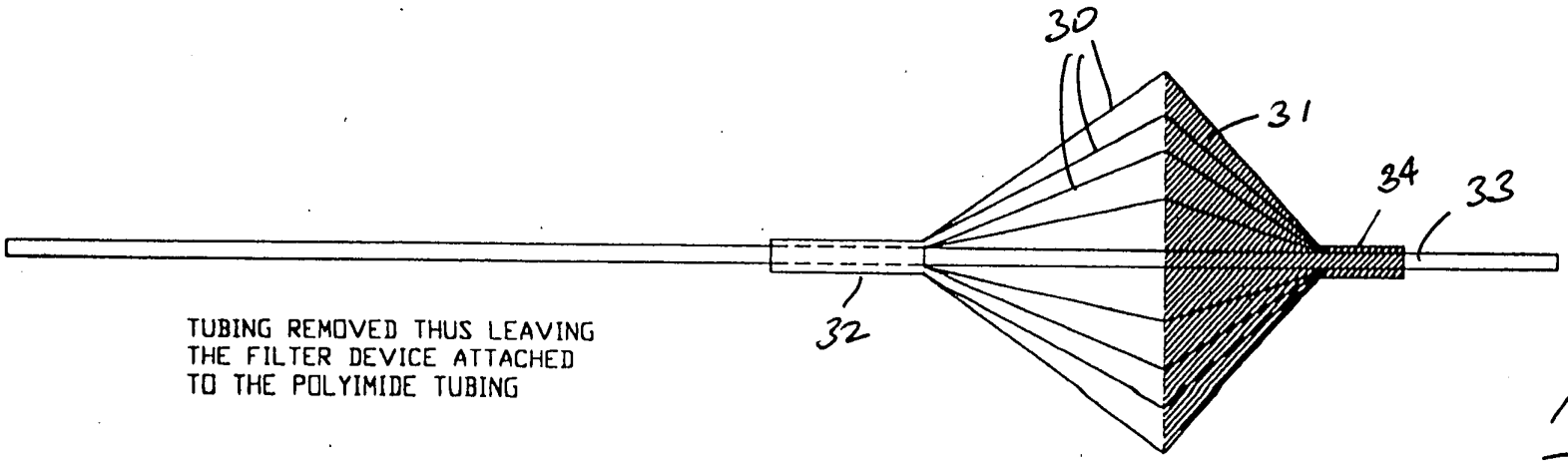


Fig. 15

Fig. 16

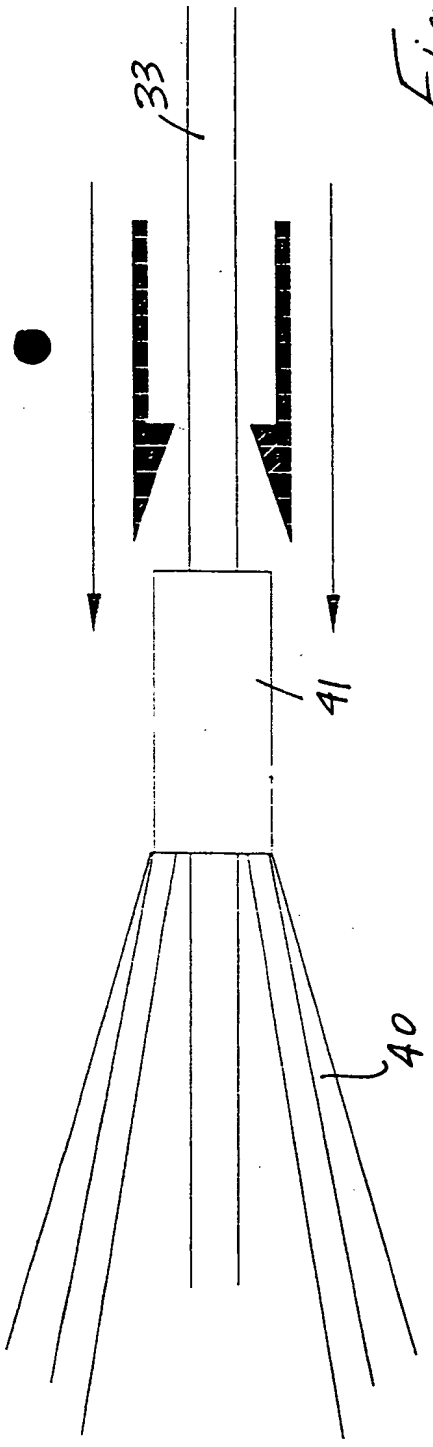
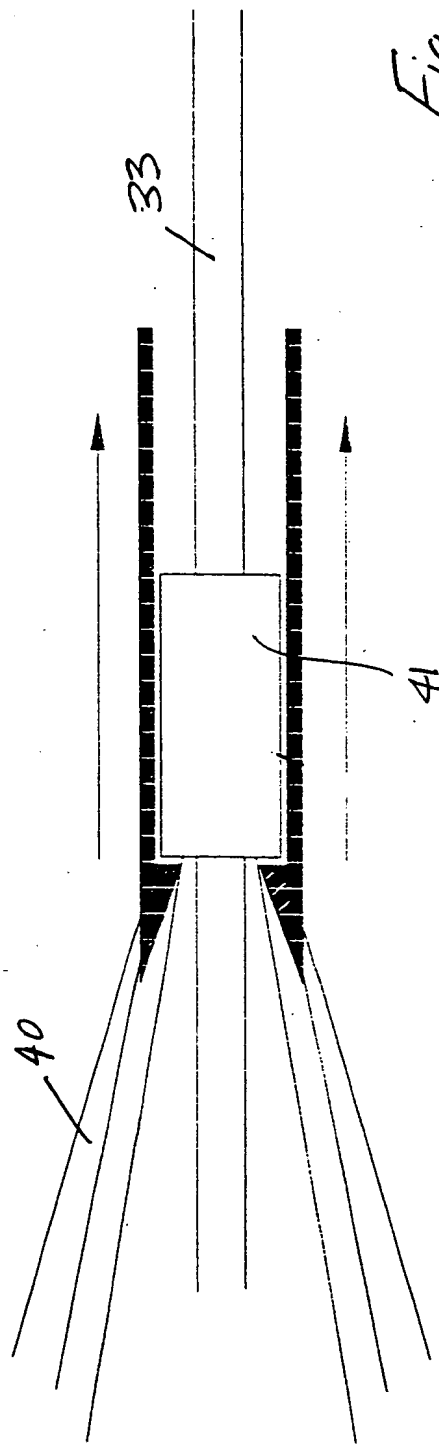


Fig. 17



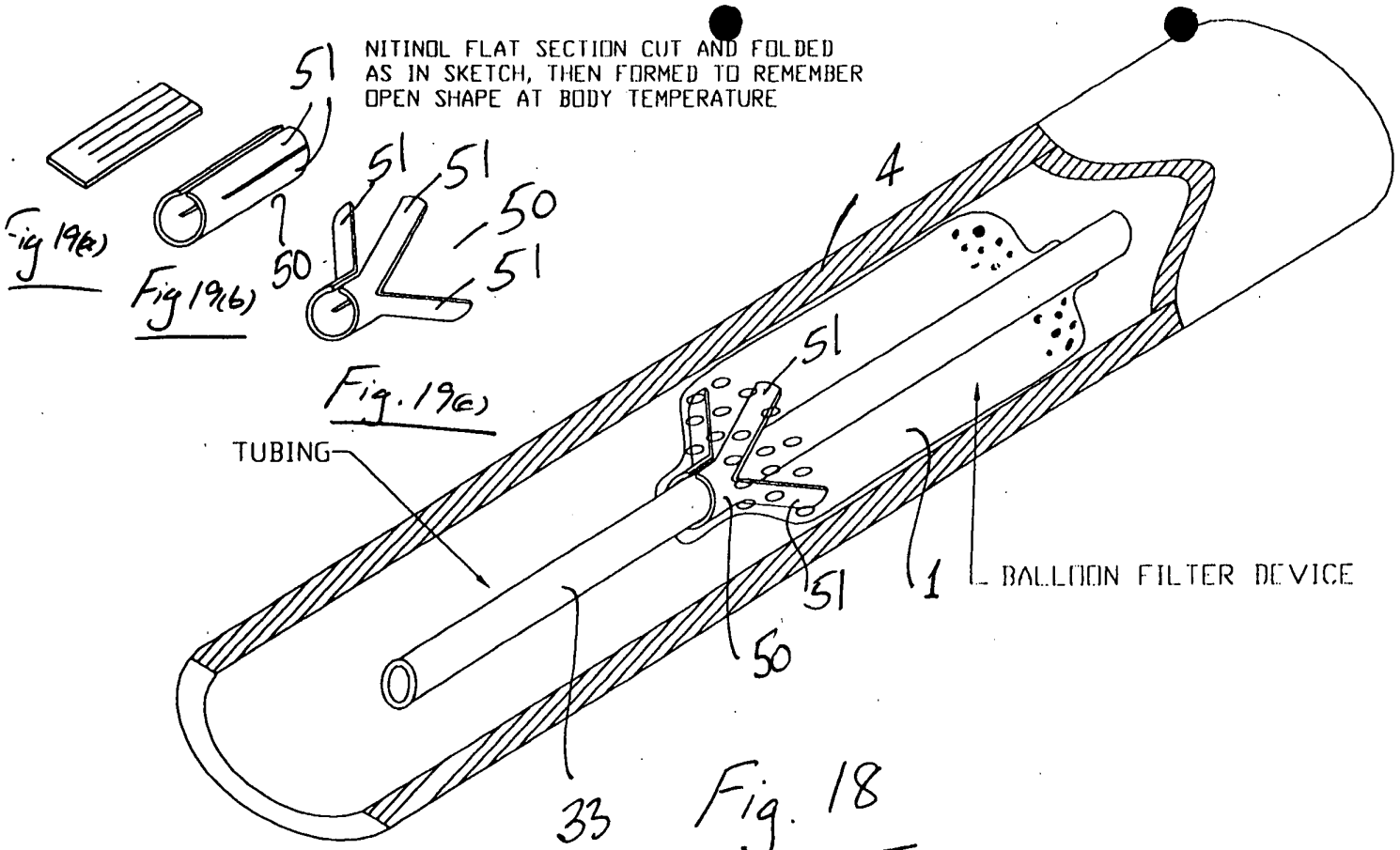

NITINOL FLAT SECTION CUT AND FOLDED
AS IN SKETCH, THEN FORMED TO REMEMBER
OPEN SHAPE AT BODY TEMPERATURE
51
Fig 19(a)
51
51
50
50
51
Fig 19(b)
Fig. 19(c)
4
51
TUBING
51
50
1
BALLOON FILTER DEVICE
33

Fig. 18

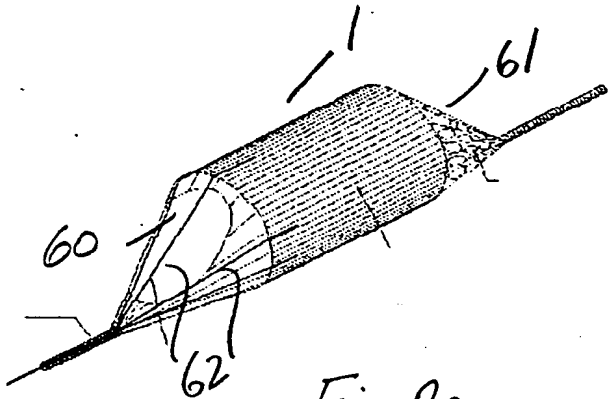
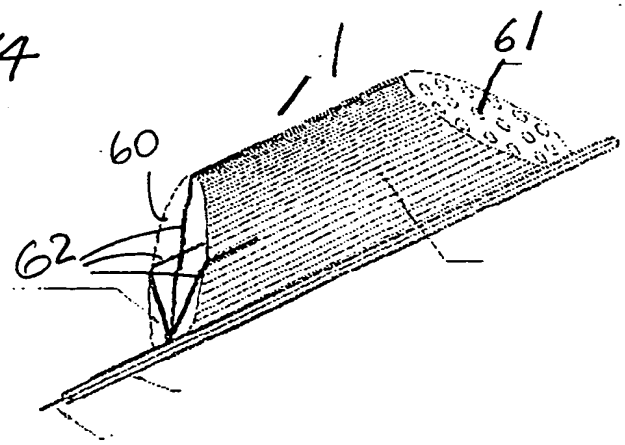


Fig.20



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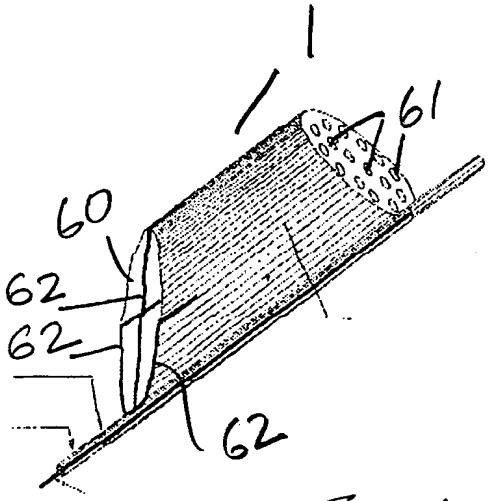

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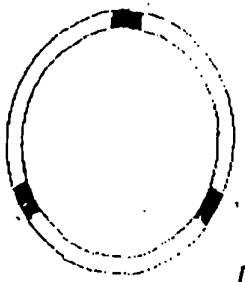
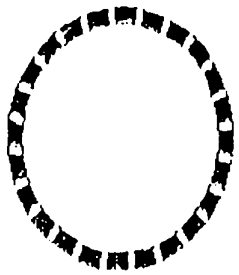


Section AA

Fig 24



Section BB

Fig 25

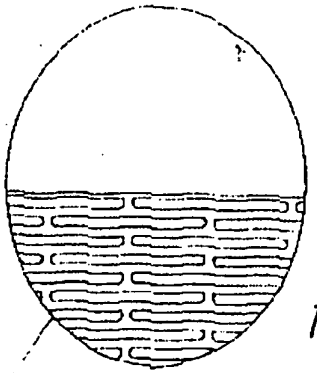
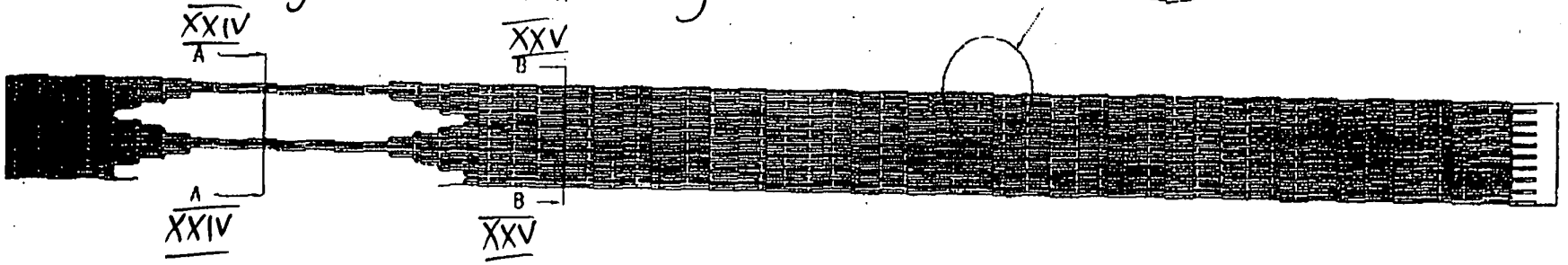


Fig 26



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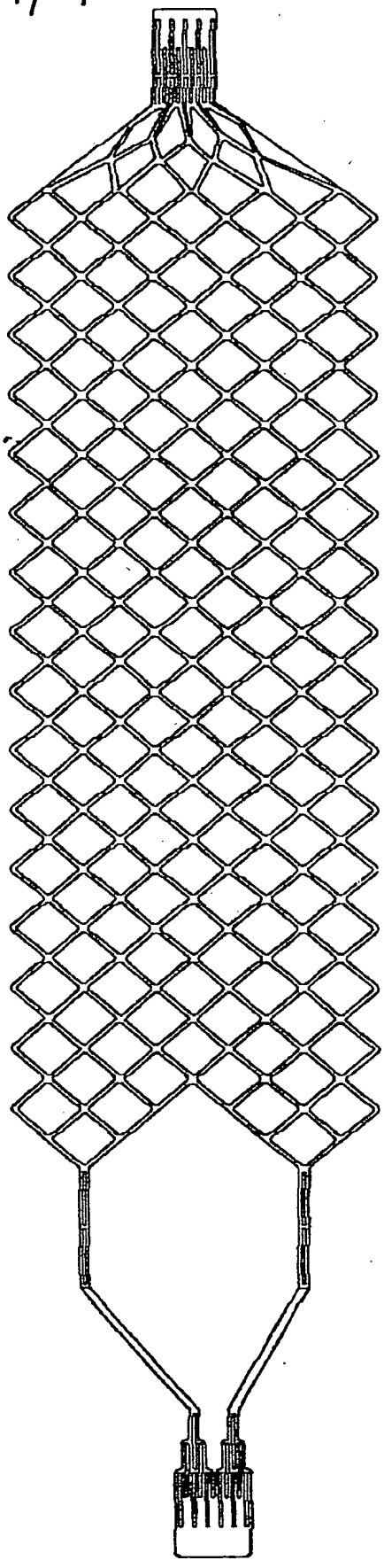

Fig 27